Remarks

A restriction requirement under 35 U.S.C. §121 and §372 was set forth in the Official Action dated March 25, 2004 in the above-identified patent application. It is the Examiner's position that claims 1-25 in the present application are drawn to six (6) patentably distinct inventions which are as follows:

Group I: Claims 1-4, 6, 7, and 11-16 drawn to SEQ ID NO: 1 and host cells and vectors comprising SEQ ID NO: 1;

Group II: Claims 5 and 17 drawn to RNA transcribed from SEQ ID NO: 1, the anti-sense complement of SEQ ID NO: 1, and host cells comprising the same;

Group III: Claims 8-10 drawn to antibodies;

Group IV: Claims 18-21 drawn to transgenic animals;

Group V: Claims 22-24 drawn to methods for screening a test compound;

Group VI: Claim 25 drawn to a kit for detecting the presence of human ABCA2-encoding nucleic acids.

Election with Traverse

In order to be fully responsive to the above-mentioned requirement, Applicants hereby elect the subject matter of Group I for consideration in this application, with the understanding that Group I includes

claims 1-4, 6, 7, and 11-16 drawn to SEQ ID NO:1 and vectors and host cells comprising SEQ ID NO:1.

Traversal

Applicants respectfully assert that the restriction requirement set forth above is improper for failure to comply with the relevant provisions of the Manual of Patent Examining Procedure (M.P.E.P.) pertaining to unity of invention determinations.

The present application was filed under 35 U.S.C. §371 as a U.S. national stage application under the Patent Cooperation Treaty.

As stated in § 1893.03(d) of the M.P.E.P.:

> Examiners are reminded that unity of invention (not restriction) practice is applicable in international applications (both Chapter I and II) and in national stage applications submitted under 35 U.S.C. § 371...
>
> The principles of unity of invention are used to determine the types of claimed subject matter and the combinations of claims to different categories of invention that are permitted to be included in a single international or national stage patent application. The basic principle is that an application should relate to only one invention or, if there is more than one invention, that applicant would have a right to include in a single application only those inventions which are so linked as to form a single general inventive concept.
>
> A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art....
>
> Note also examples 1-17 of Annex B Part 2 of the PCT Administrative Instructions as amended 01 July 1992 contained in Appendix AI of the M.P.E.P.

Notably, during the international stage of this application, in the written opinion issued October 12, 2001, the Examiner did not make a lack of unity finding and considered all of the claims to be directed to a single invention. No International Search Report was established in this case. Accordingly, there was no lack of unity finding at any stage of prosecution of the international application.

Plainly, the written restriction requirement fails to comply with the established United States Patent and Trademark Office practice of following the international rules regarding unity of invention in the prosecution of applications filed under § 371. It is unclear how the Examiner could conclude that instant application has six Groups of inventions, when the international application from which it originates has unity of invention.

Second, even if it was proper to make a lack of unity holding in the face of unity in the international application, the Examiner has improperly applied the rules for unity of invention. As the Examiner correctly points out, this application is subject to PCT Rule 13. Rule 13.2 PCT (first sentence) states:

> "Where a group of inventions is claimed in and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding technical features."

Under Rule 13 of the PCT, the only criterion to be assessed is whether the groups of claims possess either the same or a corresponding special technical feature. This inquiry must be answered in the affirmative.

Rule 13.2 provides a definition of a "special technical feature":

> "The expression 'special technical features' shall mean those technical features that define a contribution which each of the claimed invention, makes as a whole over the prior art."

The present invention relates to the nucleic acid of SEQ ID NO:1, which encodes a human ABCA2 transporter protein.

The Examiner's determination that the special technical features of the inventions he lists as Groups I-VI are allelic variants, anti-sense RNA, antibodies, transgenic animals, screening test compounds, and oligonucleotide primers represents an erroneous determination of the special technical feature.

Group I is drawn to nucleic acids of SEQ ID NO: 1 and host cells and vectors comprising SEQ ID NO: 1;

Group II is drawn to RNA transcribed from SEQ ID NO: 1, the anti-sense complement of SEQ ID NO: 1, and host cells comprising the same;

Group III is drawn to antibodies which bind to the protein encoded by SEQ ID NO:1;

Group IV is drawn to transgenic animals which express SEQ ID NO:1;

Group V is drawn to methods for screening a test compound using SEQ ID NO:1; and

Group VI is drawn to a kit for detecting the presence of human ABCA2-encoding nucleic acids comprising ABCA2 oligonucleotides which bind to a portion of SEQ ID NO:1.

Thus all of the claims require the sequence of SEQ ID NO:1, which is the special technical feature of the invention. This novel feature unifies all of the groups of invention, as described above, and as further evidenced by the finding of unity and novelty at the international stage. Accordingly, all of the claims should be examined together.

However, even if the Examiner maintains his finding that the claims lack a common novel special technical feature, at minimum, groups drawn to particular categories of invention must be searched together. See MPEP 1850A:

> The method for determining unity of invention under PCT Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:
>
> (A) In addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product;…

In the instant case, the method of Group V represents a "an independent claim for a use of the said product" of group 1, and thus should be examined in combination with group 1.

Clearly, the claims of Groups I and V as amended, are drawn to an accepted combination of categories of invention, which should always be examined together, according to PCT rule 13.2 and MPEP 1850.

Applicants also wish to point out that the inventions of Groups I (nucleic acid molecule), II (RNA-reverse transcript and anti-sense) and VI (oligonucleotide primers) should be examined together, because they are drawn to the same product. All three groups relate to nucleic acid molecules with the sequence of SEQ ID NO:1. The Examiner's determination that the sense, RNA-reverse transcript, antisense, and oligonucleotides of the same nucleic acid molecule (SEQ ID NO:1) constitute different inventions is contrary to the statutes and rules which govern restriction practice. Specifically, the MPEP clearly sets forth that:

> "There must be a serious burden on the examiner if restriction is required (see MPEP § 803.02, §

806.04(a) - § 806.04(i), § 808.01(a), and § 808.02)."

In the instant case, there is no increased search burden if Groups II and VI are searched with Group I. This is because a search of the sequence of SEQ ID NO:1 inherently encompasses the RNA-reverse transcript and antisense molecule of the same, and further also encompasses any oligonucleotide primers which represent a portion of the sequence. Thus a search of the product of Group I inherently encompasses the products of Groups II and VI, and could not represent an undue burden to the Examiner.

Finally, the Examiner's statement on pages 4-5 with regard to rejoinder is noted, and accordingly, the method claims 21-24 have been amended so that they clearly depend from the elected product of Group I. Should the restriction be maintained, and the product of Group I be allowed, applicants respectfully request rejoinder of the dependent method claims.

In light of all the foregoing, Applicants respectfully request reconsideration and withdrawal of the restriction requirement.

Applicants hereby reserve the right to file one or more continuing applications, as provided in 35 U.S.C. §120, on the subject matter of any claims finally held withdrawn from consideration in this application.

Early and favorable action on the merits of this application is respectfully solicited.

Respectfully submitted,
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